REMARKS

Claims 1-20, 22-40, and 42-57 are currently pending. No claims have been amended.

1. Rejection of Claims Under 35 U.S.C. §103(a) over Tsaur (¶2)

Reconsideration is requested of the rejection of claims 1-7, 10-18, 22-27, 30-38, 42-47, and 51-54 under 35 U.S.C. \$103(a) as being obvious over Tsaur (U.S. Patent No. 6,126,954).

Claim 1 is directed to a liquid cleanser composition comprising a lamellar structured liquid comprising from about 30% (by weight) to about 80% (by weight) of a surfactant, from about 1% (by weight) to about 30% (by weight) of a lipid phase, and from about 19% (by weight) to about 69% (by weight) water. The lipid phase comprises from about 1% (by weight) to about 5% (by weight) of a sterol and from about 95% (by weight) to about 99% (by weight) of a natural fat or oil, and the liquid cleanser composition has a viscosity of from about 10,000 cps to about 200,000 cps. The components of the lipid phase are microencapsulated.

Tsaur discloses a stable aqueous liquid comprising 5 to 45% by weight surfactant (selected from anionic, amphoteric, and nonionic), 0.1 to 5.0% by weight dispersed particles of cationic polymer, 1 to 30% by weight of a skin benefit agent emulsion having particle sizes in the range of about 0.1 to about 10 micrometers, and 1-30% by weight of water soluble skin benefit agents. Liquid stability is achieved through the interaction of dispersed cationic polymer particles and the small particle benefit agent emulsion. Upon dilution with water, the dispersed cationic particles dissolve and interact with the benefit agent

to form large oil aggregates, allowing for enhanced deposition of the benefit agent onto the skin. Significantly, Tsaur does not disclose a liquid cleanser composition having a viscosity of from about 10,000 cps to about 200,000 cps and comprising a lipid phase comprising from about 1% (by weight) to about 5% (by weight) of a sterol, wherein the components of the lipid phase are microencapsulated.

In order for the Office to show a prima facie case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. The common sense of those skilled in the art can demonstrate why some combinations would have been obvious where others would not. The Office has clearly failed to meet its burden under numbers (1) and/or (2) above, as the cited reference does not teach or suggest all of the claimed limitations and there is no apparent reason to modify the reference to arrive at each and every limitation of Applicants' claim 1. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Initially, applicants submit that Tsaur fails to disclose a liquid cleanser composition comprising from about 1% (by weight)

to about 30% (by weight) of a lipid phase, wherein the components of the lipid phase are <u>microencapsulated</u>. While Tsaur do state that their compositions may comprise 1 to 30% by weight of a skin benefit agent emulsion (which may comprise various fats and oils), there is nothing in Tsaur that suggests that the components of the skin benefit agent emulsion used therein could or should be microencapsulated. In fact, it appears from the disclosure of Tsaur that microencapsulating the components of the skin benefit agent emulsion would in fact be detrimental to the desired properties and function of the composition.

As noted above, Tsaur is directed to a stable aqueous liquid comprising a surfactant, dispersed cationic polymer particles, and small particle benefit agents. The stability of the compositions of Tsaur is achieved not through use of thickeners, but rather through the interaction of the skin benefit agent emulsion with the dispersed cationic polymer particles. The benefit agent emulsion interacts with the dispersed water soluble cationic polymer particles to form a stable network in the composition, thus acting to stabilize the skin benefit agent emulsion and prevent it from precipitating out of the solution.² It is this network, formed as a result of the interaction of the dispersed polymer particles with the emulsion of benefits agents, which is the key to the physical stability of Tsaur's liquid composition.³ For instance, Tsaur states:

¹ Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., No. 06-1402 (Fed. Cir. May
9, 2007) See also KSR Int'l Co. v. Teleflex, Inc., et al. 550 US_____, 2007
WL 1237837 at *12 (2007).

² See Tsaur at col. 3, lines 61-66.

Dispersed cationic polymer particle alone...might not be physically stable by themselves in the liquid cleanser. Without small oil droplet emulsion, these polymer particles precipitate to the bottom of the liquid composition during storage. With the addition of small oil droplet emulsion, the dispersed cationic particles interact with the oil droplet to form a stable network so that they will not precipitate out of solution even without the aid of additional structurant.⁴

Based on these disclosures in Tsaur, one skilled in the art would actually be lead away from encapsulating the components of the skin benefit agent emulsions described in Tsaur, as doing so would render the compositions of Tsaur inoperative for their intended purpose (i.e., a stable aqueous liquid). In particular, microencapsulating the components of the skin benefit agent emulsions would be expected to interfere with the ability of the emulsion to interact with the cationic polymers, thus affecting the stability of the composition. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."

Moreover, the Office has not explicitly set forth any reasons why the ordinarily skilled person would have encapsulated the components of the skin benefit agent emulsion of Tsaur. In the recently issued KSR International v. Teleflex Inc., 127 S.Ct. 1727, 1741 (2007), 82 U.S.P.Q.2d 1385, the Supreme Court has stated "it can be important to identify a reason that would have prompted a person of ordinary skill in

 $^{^{3}}$ *Id.* at col. 6, lines 62-65.

⁴ *Id.* at col. 6, line 65 to col. 7, line 6.

⁵ See MPEP \$2143.01(V), citing <u>In re Gordon</u>, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

the relevant field to combine the elements in the way the claimed new invention does." The Court also cited *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), stating: "("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")." *KSR International* at 1741. In the instant case, the Office cannot meet this burden since, considered as a whole, the Tsaur reference does not provide (and the Office cannot articulate) any reason the ordinarily skilled person would encapsulate the components of the skin benefit agent emulsion disclosed in Tsaur. Claim 1 is thus patentable over Tsaur.

Additionally, applicants note that Tsaur fails to disclose a <u>lamellar</u> structured liquid. As discussed in the specification of the present invention, the claimed liquid cleanser compositions are formulated such that the surfactant present forms a lamellar phase in solution; that is, the surfactant forms lamellar-like sheets in the solution that form together like layers of an onion that prevent the skin benefit ingredient from raising to the surface or falling to the bottom of the composition. Because the lamellar structured liquids allow for long-term suspension therein of droplets of oils, particulates, or other components, <u>emulsification of the suspended ingredient is not required</u> to keep the suspended ingredient from settling out.⁶

In contrast to the lamellar structured liquids of the present invention, Tsaur describes stable liquid cleansers that comprise a skin benefit agent emulsion. More particularly, as

noted above, Tsaur state that the dispersed polymer particles and an emulsion of benefit agents interact to provide the physical stability of the liquid composition and to keep the particles from precipitating out of the composition. There is no disclosure or suggestion of using a lamellar structured liquid to suspend benefit agents in the composition, and no suggestion that a lamellar structured liquid is desirable or even necessary to achieve stable suspension of the benefit agents.

The Office has stated that it would have been obvious that the compositions of Tsaur comprise a lamellar phase given that Tsaur teaches compositions with varying viscosities and that form dispersions or particles. Applicants respectfully disagree with this position. For one, as discussed below, Tsaur fails to disclose the viscosity of the stable compositions. The only viscosities given in Tsaur are for the pre-dispersion composition. Additionally, merely because Tsaur disclose particles dispersed in the compositions described therein does not mean the Tsaur compositions are lamellar structured liquids.

In this regard, applicants note that not all stable liquids are lamellar structured liquids. For instance WO 01/19949, cited by the Office in the present action, lists several different phases of structured liquids, stating: "As surfactant concentration increases, ordered liquid crystalline phases such as lamellar phase, hexagonal phase or cubic phase may form." WO 01/19949 goes on to describe differences between these phases. Tsaur, however, does not state that the compositions described

 $^{^6}$ See Specification at $\P14-15$.

 $^{^{7}}$ See Tsaur at col. 6, line 61 to col. 7, line 6.

⁸ See WO 01/19949 at p. 1, ln. 21-23.

⁹ Id. at p. 1, ln. 24 to p. 4, ln. 18.

therein are lamellar structured liquids, and the Office has not provided any reasoning as to why one skilled in the art would be motivated to produce a lamellar structured liquid given the disclosure of Tsaur. Claim 1 is thus patentable for this additional reason.

Additionally, Tsaur, et al. fail to disclose or suggest a liquid cleanser composition having a viscosity of from about 10,000 cps to about 200,000 cps. With regard to viscosity, the Office has stated that Tsaur teaches that the pre-dispersion compositions have a viscosity of less than 100,000 cps. however, is not the viscosity of the cleansing composition disclosed in Tsaur. As noted above, the viscosity amounts cited by the Office refers to the pre-dispersion viscosity. More particularly, Tsaur states that cationic polymer is added to the liquid cleanser as a pre-dispersion that is prepared by mixing the solid polymer with water mixable ingredients (e.g., glycerol or propylene glycol) or an aqueous solution. It is the viscosity of this pre-dispersion that is given in column 6 of Tsaur, not the viscosity of the stable aqueous liquid in which the benefit agents are suspended. There is simply no disclosure of the viscosity of the stable aqueous composition.

Furthermore, one skilled in the art would not be motivated to modify the teachings of Tsaur to arrive at a composition having applicants' claimed viscosity range. As discussed in the specification of the present invention, the stability of the structured liquid composition and the suspension of the oil or particulate skin benefit ingredient is significantly achieved by the viscosity of the liquid composition produced by the surfactant system present in the lamellar phase. Within the claimed viscosity ranges, the structured liquid cleansing

product is stable and can suspend the skin benefit ingredient therein such that emulsification is not required to keep the skin benefit ingredient in the solution. In contrast, there is nothing in Tsaur that suggests that the stability of the compositions is dependent on viscosity of the composition, and nothing that would suggest to one skilled in the art that the compositions described therein should have a viscosity within applicants' claimed range.

Additionally, Tsaur fails to disclose a lipid phase comprising from about 1% (by weight) to about 5% (by weight) of a sterol. The Office has cited to column 7, line 48 and column 18, lines 1-10 of Tsaur as teaching that the compositions of Tsaur can comprise cholesterol as a benefit agent in the amount of 1 to 30% by weight. While applicants acknowledge that Tsaur states that cholesterol may be a benefit agent, and that the compositions of Tsaur may comprise 1 to 30 wt.% of benefit agents, this is not a disclosure of applicants' claimed amounts of sterols. In particular, the composition set forth in applicants' claim 1 comprises from about 1% (by weight) to about 30% (by weight) of a lipid phase, and the lipid phase comprises from about 1% (by weight) to about 5% (by weight) of a sterol and from about 95% (by weight) to about 99% (by weight) of a natural fat and oil. There is, however, nothing in Tsaur that teaches or suggests this particular combination of components for use in the skin benefit agent emulsions described therein, nor what amount of the 1 to 30 wt.% of the benefit agents would be cholesterol. In particular, in order to arrive at applicants' claimed lipid phase, one skilled in the art would have to select from a laundry list of eleven different types of

benefit agents¹⁰ listed in Tsaur to combine lipids and fats and oils, with no guidance provided by Tsaur as to the benefits of this particular combination. One skilled in the art would then have to select cholesterol from among the listed lipids, and then determine that from 1 to 5% of the benefit agents in the benefit agent emulsion should be cholesterol and from 95 to 99% of the benefit agents in the benefit agent emulsion should be a natural fat or oil, again with no guidance provided by Tsaur as to why these selections should be made. Applicants respectfully submit that it is simply not obvious to make such a combination given the lack of guidance provided by the disclosure of Tsaur. Claim 1 is thus patentable over Tsaur for this additional reason.

In light of the foregoing, applicants submit that claim 1 is patentable over the Tsaur reference under §103(a).

Claims 2-7 and 10-18 depend directly or indirectly from claim 1 and are thus patentable over Tsaur for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

Claim 22 is similar to claim 1, except instead of a lipid phase, the composition of claim 22 comprises from about 1% (by weight) to about 30% (by weight) of a skin protectant, wherein the skin protectant is microencapsulated.

Claim 22 is patentable over Tsaur for similar reasons as those set forth above for claim 1, as well as for the additional elements it requires. In particular, Tsaur fails to disclose or suggest a liquid cleansing composition having a viscosity of

Tsaur states that preferred benefit agents include the following groups: silicone oils, gums and modifications thereof; fats and oils; waxes; hydrophobic plant extracts; hydrocarbons; esters; essential oils; lipids; vitamins; susnscreens; and phospholipids. See Tsaur at col. 7, lines 15-57.

from about 10,000 cps to about 200,000 cps and comprising a lamellar structured liquid and a <u>microencapsulated</u> skin protectant. Nor would there be any motivation for one skilled in the art to modify the teachings of Tsaur to arrive at such a composition. As such, claim 22 is patentable over the cited reference under §103(a).

Claims 23-27 and 30-38 depend directly or indirectly from claim 22 and are therefore patentable over the cited reference for the same reasons as set forth above for claim 22 as well as for the additional elements they require.

Claim 42 is similar to claim 1, except that instead of a lipid phase, the composition comprises from about 1% (by weight) to about 30% (by weight) of a microencapsulated sunscreen active.

Claim 42 is patentable over the cited reference for similar reasons as set forth above for claim 1 as well as for the additional elements it requires. In particular, Tsaur fails to disclose a liquid cleanser composition having a viscosity of from about 10,000 cps to about 200,000 cps and comprising a lamellar structured liquid and a microencapsulated sunscreen active. Nor is there any motivation to modify the teachings of Tsaur to arrive at applicants' claimed composition.

Claims 43-47, and 51-54 depend directly or indirectly from claim 42 and are thus patentable over the cited reference for the same reasons as set forth above for claim 42 as well as for the additional elements they require.

2. Rejection of Claims Under 35 U.S.C. §103(a) over Tsaur and Mitra, et al. (¶3)

Reconsideration is requested of the rejection of claims 8-9, 28-29, and 48-50 under 35 U.S.C. \$103(a) as being unpatentable over Tsaur (U.S. Patent No. 6,126,954) in view of Mitra (WO 01/19949).

Tsaur is discussed above.

Mitra, et al. disclose liquid cleansing compositions in lamellar phase, which possess a lotion-like appearance. The compositions use low salt levels in amphoteric and anionic surfactants in a structured liquid product to improve the freeze/thaw stability of the composition. Specifically, the compositions comprise a surfactant system that preferably contains at least about 5 wt.% of surface active compounds. The composition also comprises an amphoteric and/or zwitterionic surfactant present at about 3 to 30 wt.%, at least one or more anionic surfactant present at about 2 to 40 wt.%, and a lamellar structurant compound present at about 0.5 to 10 wt.%. The composition has an initial viscosity in the range of about 15,000 to 300,000 cps measured at 0.5 RPM.

Claims 8-9 depend from independent claim 1; claims 28-29 depend from independent claim 22, and claims 48-50 depend from independent claim 42. Claims 8-9, 28-29, and 48-49 further specify specific surfactants present in the claimed compositions, and claim 50 specifies specific sunscreen actives. Claims 1, 22, and 42 have not been rejected under 35 U.S.C. \$103(a) over the combination of Tsaur and Mitra, et al. Therefore, claims 8-9, 28-29, and 48-50, which depend from claims 1, 22, and 42, respectively, are patentable for the same reasons as claims 1, 22, and 42.

Applicants submit that neither of the cited references disclose or suggest microencapsulating any of the components of the compositions described therein. Furthermore, nowhere in the cited references is there motivation or suggestion to modify or combine the references to arrive at a composition wherein lipid phase components, skin protectants, or sunscreen actives are microencapsulated. For the reasons discussed above, applicants submit that one skilled in the art would actually be lead away from encapsulating the skin benefit agent emulsions described in Tsaur, as doing so would render the compositions of Tsaur unsuitable for their intended purpose (i.e., a stable aqueous liquid). Furthermore, the Mitra, et al. reference does not provide (and the Office does not articulate) any apparent reason the ordinarily skilled person would encapsulate any of the composition components described therein, or suggest or recognize any benefit in microencapsulating. As neither of the cited references provide any guidance as to microencapsulating, this element of applicants' claims 1, 22, and 42 is completely lacking in both Tsaur and Mitra, et al.

Additionally, applicants note that in general, it would not have been obvious to combine the teachings of Tsaur and Mitra, et al. as Tsaur and Mitra, et al. are in fact opposed in their teachings, and there would be no obvious way to combine the cited references. For instance, as discussed above Tsaur achieves a stable composition through interaction of cationic polymer particles and the skin benefit agent emulsions present in the composition. A structuring agent is not required. In contrast, the Mitra, et al. reference achieves a lamellar phase through use of a structuring agent, which enables the

compositions to suspend particles more readily. 12 Tsaur and Mitra, et al. thus achieve stable compositions through different mechanisms, and there is no obvious way to combine these two disparate teachings. Nor is there anything to suggest that the two means of achieving stable compositions would even be combinable.

Furthermore, with regard to claim 1, the cited references fail to disclose or suggest a liquid cleanser composition comprising a lipid phase comprising from about 1% (by weight) to about 5% (by weight) of a sterol.

Claims 1, 22, and 42 thus cannot be said to be obvious in view of the cited references. As noted above, claims 8-9, 28-29, and 48-50 depend either directly or indirectly from claims 1, 22, and 42, respectively, and are thus patentable over the cited references for the same reasons as set forth above for claims 1, 22, and 42 as well as for the additional elements they require.

2. Rejection of Claims Under 35 U.S.C. §103(a) over Tsaur and Barry, et al. (¶4)

Reconsideration is requested of the rejection of claims 19-20, 39-40, and 55-56 under 35 U.S.C. §103(a) as being unpatentable over Tsaur (U.S. Patent No. 6,126,954) in view of Barry, et al. (U.S. Patent No. 3,829,563).

Tsaur is discussed above.

Barry, et al. is directed to cleansing compositions for the hair and skin, which deposit an emollient, conditioning film thereon during washing. The compositions are oil-in-water

¹¹ See Tsaur at col. 7, ln. 3-6.

¹² See Mitra, et al. at p. 21, lines 9-16.

emulsions and may be in a liquid or semi-solid form. In particular, the compositions comprise from about 10 to about 70 percent by weight petrolatum, from about 5 to about 30% by weight of one or more organic foaming detergents, from about 1 to about 10 percent by weight of an emulsifier, from about 0.5 to about 5 percent by weight of an organic foam stabilizer, from about 0 to about 20 percent by weight of one or more emollient substances other than petrolatum, and water.

Claims 19-20 depend from independent claim 1; claims 39-40 depend from independent claim 22, and claims 55-56 depend from independent claim 42. Claims 19-20, 39-40, and 55-56 further specify that the liquid cleanser composition comprises from about 0.1% (by weight) to about 4% (by weight) of a surfactant having an HLB of from about 4 to about 8 (claims 19, 39, and 55), and set forth specific examples of such surfactants (claims 20, 40, and 56). Claims 1, 22, and 42 have not been rejected under 35 U.S.C. §103(a) over the combination of Tsaur and Barry, Therefore, claims 19-20, 39-40, and 55-56, which depend from claims 1, 22, and 42, respectively, are patentable for the same reasons as claims 1, 22, and 42. In particular, the cited references fail to disclose or suggest a liquid cleanser composition having a viscosity of from about 10,000 cps to about 200,000 cps and comprising a lamellar structured liquid, and fail to disclose or suggest microencapsulation of any of the components of the compositions described therein. Furthermore, no where in the cited references is there motivation or suggestion to modify or combine the reference to arrive at each and every limitation of claims 1, 22, and 42.

As discussed above, the liquid cleanser compositions of the present invention are formulated such that the surfactant

present forms a lamellar phase in solution. This allows for long-term suspension of droplets of oils, particulates, or other components <u>without emulsification</u> of the suspended ingredient.¹³

In contrast to the lamellar structured liquids of the present invention, Tsaur describes stable liquid cleansers that comprise a skin benefit agent emulsion. More particularly, Tsaur state that the dispersed polymer particles and an emulsion of benefit agents interact to provide the physical stability of the liquid composition and to keep the benefit agents from precipitating out of the composition. There is no disclosure or suggestion of using a lamellar structured liquid to suspend agents in the composition.

Nor do Barry, et al. disclose or suggest compositions comprising lamellar structured liquids. As noted above, Barry, et al. is directed to oil-in-water <u>emulsions</u> that may be used as cleansing compositions. There is no disclosure or suggestion anywhere in Barry, et al. that the compositions described therein could or should comprise lamellar structured liquids. With regard to the stability of the compositions in Barry, et al., Barry, et al. state that the particle size distribution of the oil phase of the oil-in-water emulsions must be within certain limits for maximum physical stability and functional efficacy. 14

Additionally, neither of the cited references disclose or suggest compositions having a viscosity of from about 10,000 cps to about 200,000 cps. As discussed above, the only disclosure of a viscosity in Tsaur is on column 6, which refers to the viscosity of the pre-dispersion, not the viscosity of the stable

 $^{^{13}}$ See Specification at $\P14-15$.

¹⁴ See Barry, et al. at col. 2, lines 12-15.

aqueous liquid in which the skin benefit agents are suspended. There is simply no disclosure of the viscosity of the stable aqueous composition in Tsaur. Nor do Barry, et al. provide any guidance as to the viscosity of the oil-in-water emulsions described therein. Additionally, applicants note that neither of the cited references recognizes the benefits of compositions having a viscosity as set forth in applicants' claims, and in particular fail to recognize the relationship between viscosity and formation of lamellar structured liquids.

Nor do Tsaur or Barry, et al. teach or suggest encapsulating any of the composition components described therein. If anything, the combination teaches away from encapsulating composition components. As discussed above, one skilled in the art would be lead away from encapsulating the components of the skin benefit agent emulsions disclosed in Tsaur, as it would appear that doing so would render the compositions of Tsaur unsuitable for their intended purpose by interfering with the ability of the benefit agent emulsions to interact with cationic polymer particles present in the composition and the formation of a stable aqueous liquid. Barry, et al. does nothing to contradict this teaching, as Barry, et al. fails to disclose encapsulation or recognize any benefit in encapsulation.

Since neither Tsaur nor Barry, et al. teach or suggest compositions comprising lamellar structured liquids, compositions having the claimed viscosity, or microencapsulation, applicants submit claims 1, 22, and 42 are patentable over the cited references.

As noted above, claims 19-20, 39-40, and 55-56 depend from claims 1, 22, and 42, respectively, and are therefore patentable

KCC 4980 (K-C 19,319) PATENT

over the cited references for the same reasons as set forth above for claims 1, 22, and 42 as well as for the additional elements they require.

CONCLUSION

In view of the above, Applicants respectfully request favorable reconsideration and allowance of all pending claims. The Commissioner is hereby authorized to charge any fee deficiency in connection with this Response After RCE to Deposit Account Number 19-1345 in the name of Senniger Powers.

Respectfully submitted,

/Christopher M. Goff/

Christopher M. Goff, Reg. No. 41,785 SENNIGER POWERS One Metropolitan Square, 16th Floor St. Louis, Missouri 63102 (314) 231-5400

LJH/cms By EFS